DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

1/29/98

D1053B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

**WARNING LETTER**

FLA-98-13

December 16, 1997

Claude B. Matasa, President
Ortho-Cycle Company, Inc.
2026 Scott Street
Hollywood, Florida 33020

Dear Mr. Matasa:

We are writing to you because on July 8-17, 1997, FDA Investigator Michelle S. Dunaway collected information that revealed serious regulatory problems involving orthodontic appliances (Class I), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to verify and/or validate remanufacturing and sterilization processes for metal and ceramic brackets and bands, e.g., (1) adhesive removal, ultrasound wash, electro-polishing, and silane application; (2) steam sterilization equipment and processes using the "new" autoclave, which was first used in 1994 and the "old" autoclave, which has not been revalidated since the initial validation was conducted in 1991 both of which are used

to sterilize metal and ceramic brackets and metal bands, and (3) pH test to determine devices are adequately rinsed.

- Failure to include in the Device Master Record for metal brackets and bands required information that is formally approved, e.g., process times required to complete the rinsing process after electro-polishing metal brackets and bands, and the process parameters for steam sterilization; and for ceramic brackets required information that is formally approved, e.g., silanation procedures, the results of QA testing performed on batches of silane treated brackets, and the steam sterilization process parameters.

- Failure to establish, implement, maintain and conduct planned and periodic audits of the Quality Assurance program.

- Failure to establish and maintain written procedures for Medical Device Reporting (MDR), complaint handling, corrective and preventive actions, and the evaluation, investigation, and disposition of nonconforming product.

- Failure to maintain Device History Records for metal and ceramic brackets and metal bands that demonstrate the actual manufacturing processes conform to specifications.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA-483), issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when

you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at http://www.fda.gov.

Your written response dated July 24, 1997 was reviewed and found to be inadequate to fully address the investigator's observations because it fails to provide specific corrections including documentation necessary for our review to determine the adequacy of your corrective actions, e.g., validation of sterilization procedure, recording of pH tests to determine the residue of acid that may remain on devices after electro-polishing, and examples of newly established and implemented documentation used to record actual processes and test results.

If you have more specific questions about the Quality System Regulation and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,

Michael A. Chappell
Acting Director
Florida District